



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293203	MediHerb Herbal Throat Spray
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	25/08/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . MediHerb Herbal Throat Spray

Product Type	Single Medicine Product	Effective Date	31/01/2019
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Decrease/reduce bacteria in the mouth

Decrease/reduce/relieve mouth/oral mucosa mild inflammation

Traditionally used in Western herbal medicine to decrease/reduce/relieve mouth/oral mucosa mild inflammation

Traditionally used in Western herbal medicine to soothe/relieve mouth/oral irritation

Traditionally used in Western herbal medicine to maintain/support oral mucous membrane health

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild mouth ulcers

Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues

Traditionally used in Western herbal medicine to relieve dry unproductive cough

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild throat inflammation

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild throat infection

Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation

Traditionally used in Western herbal medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation

Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild tonsillitis

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious infections.

Product presentation must not imply or refer to recurrent or persistent mouth lesions.

Product presentation must only refer to mild mouth ulcers.



Australian Government
Department of Health
 Therapeutic Goods Administration

Product presentation must only refer to mild tonsillitis.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Spray, solution

Route of Administration Oral

Visual Identification

Active Ingredients

Althaea officinalis root Extract liquid	400 microlitre/mL
Equivalent: Althaea officinalis (Dry)	80 mg/mL
Calendula officinalis flower Extract liquid	40 microlitre/mL
Equivalent: Calendula officinalis (Dry)	20 mg/mL
Clove Bud Oil	2.5 microlitre/mL
Commiphora myrrha stem bark oleoresin Extract liquid	10 microlitre/mL
Equivalent: Commiphora myrrha (Dry)	2 mg/mL
Echinacea angustifolia root Extract liquid	40 microlitre/mL
Equivalent: Echinacea angustifolia (Dry)	20 mg/mL
Salvia officinalis herb Extract liquid	120 microlitre/mL
Equivalent: Salvia officinalis (Dry)	60 mg/mL

Other Ingredients (Excipients)

ethanol

Lemongrass Oil

menthol

methyl hydroxybenzoate

potassium sorbate

propyl hydroxybenzoate

purified water

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.